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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/439,534	11/12/1999	SIMON GEIR MOLLER	2312-103	1755

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/07/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/439,534

Applicant(s)

MOLLER ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-46, 59, 60 and 72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-46, 59, 60, and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 39-46, 59, 60, and 72 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vectors wherein the transcription factor and promoter of the inducible gene are based on the GVG system, and wherein the vector is a plant transformation vector, does not reasonably provide enablement for vectors comprising all transcription factors and inducible promoter systems and non-plant vectors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed 25 February 2002 under item 8. Applicants traverse the rejection in the paper received 25 June 2002. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the enablement requirement is met if the specification teaches even a single means for carrying out the invention, and that an applicant is not required to recite specifically each and every means of carrying out the invention, so long as the specification provides sufficient guidance to the person of ordinary skill in the art to practice an embodiment of the invention without the need for undue experimentation (response, paragraph bridging pages 2-3). Applicants argue that requiring Applicants to list each and every inducible promoter that

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could function in the claimed invention is an unnecessary and unreasonable burden, and that examples of other inducible promoters are provided in the specification, and cite page 5, lines 14-18 (response, paragraph bridging pages 3-4). One of the promoters listed is the heat shock promoter system. However, Applicants themselves have admitted that the heat shock promoter is not suitable for use with their invention (response received 10 December 2001, paragraph bridging pages 14-15). Given that Applicants have admitted that a promoter, that was specifically recited in the specification, cannot be used with the claimed invention, it is not clear what other promoters, including other promoters specifically cited in the specification, can be used with the claimed invention. Applicants have stressed that the heat shock promoter cannot be used with the claimed invention because it does not provide a tight enough control over transcription. However, the specification does not teach what other promoters besides the GVG system would provide this control. Applicants argue that the specification need only teach a single means for carrying out the invention, and that the specification provides sufficient guidance. However, Applicants themselves have argued that the heat shock promoter cannot be used with the instant invention, although the specification teaches to do just that. It is not clear what other teachings of the specification fail to enable the invention.

Applicants argue that the Patent Office has provided no evidence, and no reasoning beyond a bare assertion, that the type of experimentation required to practice the claimed invention would require knowledge and skill beyond that of the ordinary practitioner, and that absent such evidence or reasoned argument, statements in the specification must be taken as true and correct (response, paragraph bridging pages 4-5). However, as discussed above, Applicants themselves have argued that a teaching of the specification is not enabled.

Applicants also argue that all of the elements of the claimed vectors are known to function in organisms other than plants, and there is nothing in the specification to limit the invention solely to use in plants (response, page 6, 1st full paragraph). However, the specification itself at page 3, lines 10-13, under the heading "SUMMARY OF THE INVENTION," teaches that the invention is directed for use in transgenic plants.

Claim Rejections - 35 USC § 103

3. Claims 39-44, 59, 60, and 72 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sugita et al. (U.S. Patent No. 6,326,192) in view of Aoyama et al. (Plant J., 1997, Vol. 11, pages 605-612), for the reasons of record stated in the Office action mailed 25 February 2002 under item 9. Applicants traverse the rejection in the paper received 25 June 2002. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that the Office found motivation to combine Sugita with Aoyama in the mention of Sugita of a "glucocorticoid system promoter," and that this is not sufficient because all Sugita does is mention a glucocorticoid system promoter in a long list of inducible promoter systems, and there still remains nothing in the combined references that would lead a person of ordinary skill in the art to select that particular promoter. Applicants argue that therefore impermissible hindsight was used (response, page 10, 1st full paragraph to the paragraph bridging pages 11-12). However, the presence of the glucocorticoid promoter system in the list of inducible promoters cited by Sugita et al. was not the only motivation provided to include it in the vector. The rejection also cited advantages provided by the system, as taught by Aoyama et al.

Applicants argue that the broadest claims recite “a transcription factor,” not a “glucocorticoid system promoter,” and that citation to a “glucocorticoid system promoter” does not suggest the use of transcription factors generally. Applicants argue that the markers and method of the claims are not limited to use in plants, and Sugita, in contrast, teaches a system using a very specific kind of marker- a morphological abnormality gene, that can only be used in plants (response, paragraph bridging pages 12-14). However, all of these embodiments are encompassed by the claims. The claims do not limit the type of marker gene that can be used, or that all of the encompassed vectors must be capable of use with all types of cells regardless of species, or that the method is to be applicable only to non-plant organisms. Further, as mentioned above, the specification teaches that the invention is to be used in plants, and the method claims indicate that the method is for use in plant cells. It is not clear why Applicants are arguing that the marker genes of Sugita can only be used in plants, when the claimed method indicates that the method is for use in transgenic plants or plant cells.

Applicants again argue that Sugita uses only morphological abnormality genes as markers and does not suggest the use of transcriptions factors in general, nor does it teach using the vectors in non-plant organisms (response, paragraph bridging pages 14-15). However, again, the claims broadly encompass any marker gene. The glucocorticoid system taught by Aoyama et al. includes the use of a transcription factor. Further, there is no requirement that each and every one of the vectors encompassed by the claimed invention must be usable in all organisms.

Applicants also argue that with the present system it is possible to achieve excision in germ-line cells, thereby permitting transmission of the “excised” phenotype to subsequent generations. In the prior art, the excision was only carried out in somatic cells, and that there is

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no indication, or reasonable expectation, that the Sugita system in view of Aoyama would cause excision in germ-line cells. Applicants also argue that the present system can be used to activate a silent gene, by removal of a “stuffer,” situated between a silent gene and its promoter, and that this advantage is not hinted at in the cited combination of references. However, again, there is no limitation in the claims that the method is to only be practiced in germline cells, and the claims do not mention any “stuffer” fragments. See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Applicants also argue that there has been an long-felt but unmet need in the art for a system such as that of the present claims, yet in the three years between the publication of the Sugita patent and the filing of the instant application, no person was led to make the combinations and modifications to the art that are suggested by the Patent Office (response, paragraph bridging pages 16-17). However, Applicants provide no evidence of such a long-felt need or that others in the art have tried and failed to solve the supposed problem or produce Applicants' invention. See MPEP 716.04. The rejection is maintained.

4. Claim 45 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sugita et al. (U.S. Patent No. 6,326,192) in view of Aoyama et al. (Plant J., 1997, Vol. 11, pages 605-612) as applied to claims 39-44, 59, 60, and 72 above, and further in view of Albert et al. (Plant J., 1995, Vol. 7, pages 649-659), as stated in the Office action mailed 25 February 2002 under item 11. Applicants traverse the rejection in the paper received 25 June 2002. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the Albert et al. reference does nothing to overcome the basic deficiencies of the Sugita and Aoyama references discussed in the traversal of the 103 rejection above, and that this combination of references cannot render the present claims obvious (response, page 17, 2nd full paragraph). However, it is not believed that the combination of the Sugita and Aoyama references suffer from the supposed deficiencies, for the reasons discussed above. The rejection is maintained.

Summary

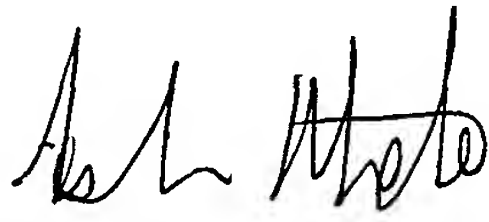
5. Claims 39-46, 59, 60, and 72 remain rejected.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

January 3, 2003